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#7/55
12-8-03PATENT

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT : CLARK ET AL.
SERIAL NO. : 10/026,852
FILED : DECEMBER 21, 2001
TITLE : ORAL MEDICAL DISPENSER
EXAMINER : LINA KONTOS
ART UNIT : 3763

CLAIM OF PRIORITY

Honorable Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

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TECHNOLOGY CENTER R3700

Dear Sir:

Applicant herewith claims the benefit of priority of his earlier-filed application under the International Convention in accordance with 35 U.S.C. 119. Applicant also submits a certified copy of the patent application, having the Application No. 9914621.9, which bears the application date of June 23, 1999.

Respectfully submitted,

Thomas M. Galgano, (27,638)
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Attorneys for Applicant
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TMG/jgg

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first-class mail in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on November 26, 2003.

By:

Thomas M. Galgano, Esq.

Dated: November 26, 2003

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In accordance with the Patents (Companies Re-registration) Rules 1982, if a company named in this certificate and any accompanying documents has re-registered under the Companies Act 1980 with the same name as that with which it was registered immediately before re-registration save for the substitution as, or inclusion as, the last part of the name of the words "public limited company" or their equivalents in Welsh, references to the name of the company in this certificate and any accompanying documents shall be treated as references to the name with which it is so re-registered.

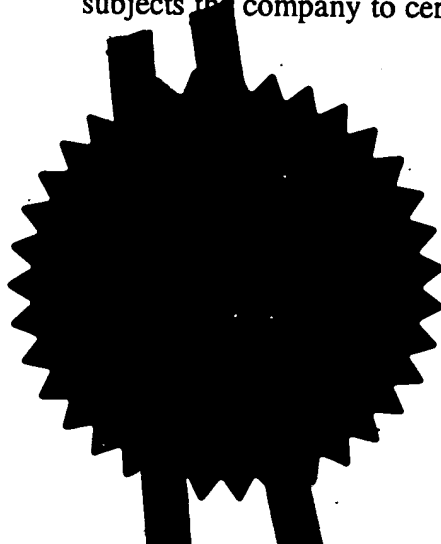
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Signed

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THE PATENT OFFICE

A

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23JUN99 E456725-2 D00790
P01/7700 0.00 - 9914621.9

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road

Newport

Gwent NP9 1RH

23 JUN 1999

1. Your reference

PA 3362

2. Patent application number

(The Patent Office will fill in this part)

9914621.9

3. Full name, address and postcode of the or of each applicant (underline all surnames)

EU Pharma Ltd
17 Granville Road
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Herts
EN5 4DU

Patents ADP number (if you know it)

If the applicant is a corporate body, give the country/state of its incorporation

United Kingdom

768661100/m3

4. Title of the invention

Oral Medicine Dispenser

5. Name of your agent (if you have one)

"Address for service" in the United Kingdom to which all correspondence should be sent (including the postcode)

SOMMERVILLE & RUSHTON

45 Grosvenor Road
St Albans
Herts
AL1 3AW

Patents ADP number (if you know it)

1511001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and (if you know it) the or each application number

Country

Priority application number
(if you know it)

Date of filing
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7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application

Date of filing
(day / month / year)

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? (Answer 'Yes' if:

- a) any applicant named in part 3 is not an inventor, or
- b) there is an inventor who is not named as an applicant, or
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Yes

See note (d))

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form

6	Description
2	Claim(s)
1	Abstract
1	Drawing(s)

10. If you are also filing any of the following, state how many against each item.

Priority documents

Translations of priority documents

Statement of inventorship and right to grant of a patent (Patents Form 7/77)

Request for preliminary examination and search (Patents Form 9/77)

Request for substantive examination (Patents Form 10/77)

Any other documents
(please specify)

11. I/We request the grant of a patent on the basis of this application.

Signature

Date

23 June 1999

12. Name and daytime telephone number of person to contact in the United Kingdom

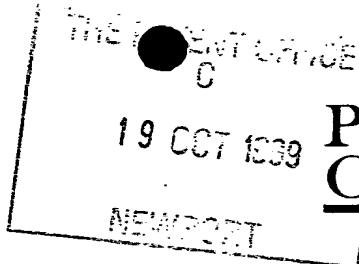
IAIN WHITAKER
01727 854215

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Replacement

7/77

Statement of inventorship and of right to grant of a patent

The Patent Office

Cardiff Road
Newport
Gwent NP9 1RH

1. Your reference	PA 3362
2. Patent application number (if you know it)	9914621.9
3. Full name of the or of each applicant	<u>EU Pharma Ltd</u>
4. Title of the invention	Oral Medicine Dispenser
5. State how the applicant(s) derived the right from the inventor(s) to be granted a patent	By virtue of section 39(1) of the Patents Act 1977
6. How many, if any, additional Patents Forms 7/77 are attached to this form? (see note (c))	1
7.	<p>I/We believe that the person(s) named over the page (and on any extra copies of this form) is/are the inventor(s) of the invention which the above patent application relates to.</p> <p>Signature  Date 18 October 1999</p>
8. Name and daytime telephone number of person to contact in the United Kingdom	IAIN WHITAKER 01727 854215

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Patents Form 7/77

Enter the full names, addresses and postcodes of the inventors in the boxes and underline the surnames

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Reminder

Have you signed the form?

DUPLICATE

ORAL MEDICINE DISPENSER

Field of the Invention

The present invention relates to an oral medicine dispenser that is adapted for administration of a single pre-measured dose.

5 Background to the Invention

Administration of liquid oral medicaments to small children, the elderly and infirm can be a difficult task to execute correctly using the conventional measuring spoon and supply of medicament in a tamper-proof or tamper-evident bottle. Not only is there the difficulty of accurately filling the spoon to the required dose but more problematically,
10 there is the substantial risk that the patient may not properly consume the dose held in the head of the spoon. Particularly with children, spillages are frequent.

Further problems with the use of a bottle of medicament and dosing spoon are the need for inclusion of preservatives in the medicament which in turn leads to risk of allergenic sensitisation against the preservatives, especially in young children and
15 babies.

Among the many further limitations of the conventional bottle and spoon are the difficulties of making the container effectively tamper evident, keeping costs to a minimum and avoiding build-up of residues around the neck of the bottle. Many liquid oral medicaments are in syrup form and have a tendency to congeal around the bottle
20 neck.

Prior art proposals for alternatives to the conventional bottle and spoon have included disposable single pre-measured dose containers. One example of such a container is illustrated in European Patent Application EP 0 778 018 A1 and comprises a spoon-shaped peel-off container having a hollow thermo-formed body holding the
25 single dose of medicament and which is sealed in by a peel-off film or foil. The body has a short flat extension for use as a handle.

A similar device for administration of a single pre-measured dose is illustrated in UK Patent Application GB 2 306 322 A and comprises a spatula-like element having a rupturable medicament container fastened to the base of the device. The container is ruptured upon withdrawing the device between the teeth or lips of the patient to
5 discharge the contents into the mouth of the patient.

Whereas these prior art devices partially address the problems associated with the conventional bottle and spoon they do not resolve such problems as the risk of spillage of the medicament and not giving full control over administration to the holder of the device, amongst others.

10 It is the general objective of the present invention to provide an improved oral medicine dispenser for administration of a single pre-measured dose and which mitigates against or overcomes some or all of the aforementioned and other problems of the prior art.

Summary of the Invention

15 According to the present invention, there is provided an oral medicine dispenser for the administration of a single pre-measured dose, which dispenser comprises a body having a collapsible reservoir portion and an elongate dispensing tube portion extending from the reservoir portion, wherein the reservoir portion holds, in use, a single dose of a fluid oral medicament and the dispensing tube portion has an end cap, whereby on
20 opening of the end cap the collapsible reservoir portion may be manually squeezed to collapse the reservoir portion sufficiently to dispense substantially all of, or at least the major part of, the medicament dose through the dispensing tube portion.

The end cap of the dispensing tube portion is suitably a frangible or severable end part of the dispensing tube portion.

25 The dispenser is preferably sufficiently transparent to enable viewing of its contents although it may be coloured - for example colour coded to reflect aspects of its

medicament contents. It is preferably of substantially unitary construction and is suitably formed of a plastics material by a form, fill and seal technique in which a plastics material is formed to substantially the required shape and with an opening to introduce the fluid oral medicament, the opening then being sealed.

5 A particularly preferred form of the device is shaped to resemble a spoon, at least in profile. That part of the dispenser which resembles the head of a spoon is the reservoir portion and that part of the dispenser which resembles the handle of the spoon is the dispensing tube portion. In practical terms, however, that part which resembles the handle of a spoon does not have the function of a handle. The primary mode of use
10 of the dispenser involves handling it by the reservoir portion for the dispensing of the medicament. The purpose of forming the dispenser to resemble a spoon is not that it may perform the function of a spoon but rather that the profile shape is surprisingly convenient for the purpose of squeeze-dispensing the medicament. Indeed, the reservoir portion provides for a more secure handle than that of a spoon. Furthermore,
15 the similarity of appearance to the shape of a spoon is comfortingly reassuring to the patient.

The reservoir portion of the dispenser is preferably generally hemispherical or at least having a substantially flat wall on one face and an opposing substantially domed wall. This flattened bulb shape ties in well with the preferred spoon-shaped profile and
20 also facilitates manufacture, reducing spillage during filling of the dispenser in manufacture while enabling the reservoir to be relatively easily squeezed to collapse and dispense the medicament.

The internal wall(s) of the reservoir portion is/are suitably rounded to mitigate against the risk of entrapment of any medicament.

25 The dispenser of the present invention is economical to manufacture and simple, fun and straightforward to use with minimal spillage and minimal residue and is

especially suitable for administration of syrupy medicaments to infants, the elderly and the infirm.

Brief Description of the Drawings

A preferred embodiment of the present invention will now be more particularly
5 described, by way of example, with reference to the accompanying drawings, wherein:-

Figures 1 and 2 are, respectively, a side elevation view and a top plan view of the preferred embodiment of dispenser; and

Figure 3 is a longitudinal sectional view of the preferred embodiment.

Description of the Preferred Embodiment

10 As will be seen from the accompanying figures, the preferred embodiment has the general shape of a spoon when viewed in profile and, for that matter, having the outline of a spoon when viewed in plan. However, as may be clearly seen from the sectional view, that portion of the dispenser which resembles the head of the spoon is a
reservoir bulb 1 having a flat upper surface 2. That portion of the dispenser which
15 resembles the handle of a spoon is a dispensing tube 3.

The preferred embodiment of dispenser illustrated is formed by a blow-fill and seal technique in which low density polyethylene, or similar, polymer beads are melted and extruded and during the extrusion blown into the required form with nitrogen gas or other, preferably inert, gaseous medium. An opening is left in the moulding to allow the
20 oral medicament to then be introduced into the hollow interior of the dispenser. For obvious reasons, this opening is suitably formed in the upper surface of the dispenser moulding, containing the liquid oral medicament therewithin until the opening is sealed.

The entirety of the dispenser is formed in this single moulding process. Accordingly, the reservoir bulb portion 1 and dispensing tube portion 3 have a unitary
25 construction.

Provision is made for straightforward opening of the tip 4 of the dispensing tube portion 3 by snapping/tearing, cutting or otherwise detaching or releasing the end of the tubular portion 3. In its simplest form, this may be achieved by a thinning of the moulding at a suitable pre-breakage line 5 extending around the "circumference" of the tubular portion 3. This pre-breakage line may be introduced as a relatively thinner section of the tubular portion during the moulding process or may be subsequently scored onto the moulding.

The thus-formed dispenser suitably has a capacity equivalent to that of any conventional dose measuring spoon and which may deliver of the order of 2.5 – 10ml of the medicament and preferably of the order of 5ml.

The construction of the reservoir bulb portion 1 is such as to enable it to relatively straightforwardly be squeeze compressed between thumb and forefinger to reliably expel substantially the whole contents of the reservoir bulb portion 1 and tubular portion 3 through the opened end of the tubular portion 3. Little medicament residue need be left behind and the dispenser may be disposed of following use.

The action of removing the end portion/cap or tip 5 of the dispenser is perhaps most conveniently carried out by holding the tubular portion 3 close to the score-line 4 and with the reservoir bulb portion 1 lowermost and then simply snapping or cutting off the end portion of the dispensing tube portion 3 of the dispenser.

During construction of the dispenser it may be desirable to reinforce the tubing portion 3 by, for example, configuring the moulding so that the tubular dispensing portion 3 has a somewhat thicker cross-section than the reservoir bulb portion 1 to give it greater rigidity than the reservoir bulb portion 1. The reservoir portion 1 must inherently have an adequate flexibility to optimise the dispensing action but this is less important for the dispensing tube portion 3 and it is useful to be able to grip the tube portion 3 firmly without squeezing it when severing the tip 4.

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The volume of medicament enclosed within the dispenser may suitably be slightly greater than the required dose to allow for any part of the dispensing tube portion 3 that may not be fully collapsible.

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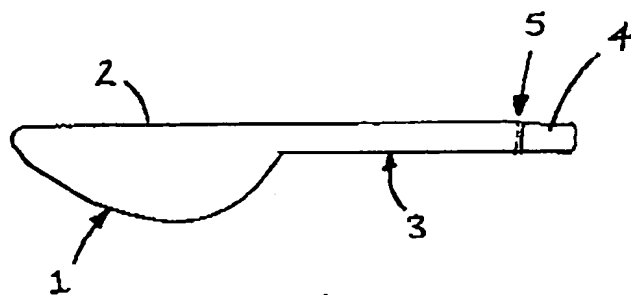


FIGURE 1

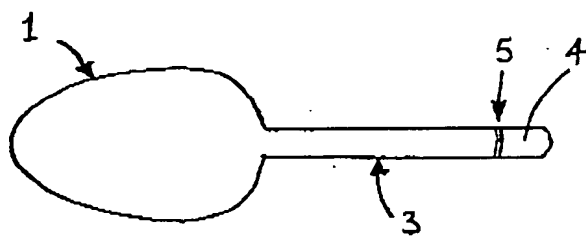


FIGURE 2

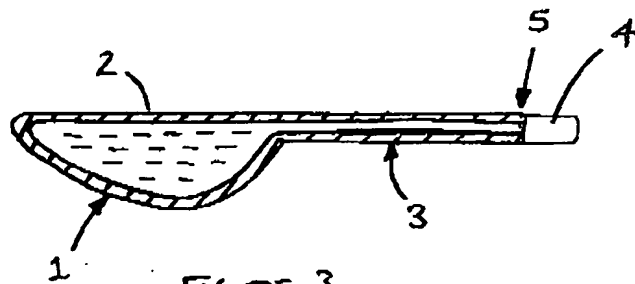


FIGURE 3

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CLAIMS

1. An oral medicine dispenser for the administration of a single pre-measured dose, which dispenser comprises a body having a collapsible reservoir portion and an elongate dispensing tube portion extending from the reservoir portion, wherein the
5 reservoir portion holds, in use, a single dose of a fluid oral medicament and the dispensing tube portion has an end cap, whereby on opening of the end cap the collapsible reservoir portion may be manually squeezed to collapse the reservoir portion sufficiently to dispense substantially all of, or at least a major part of, the medicament dose through the dispensing tube portion.
10
2. An oral medicine dispenser as claimed in claim 1 wherein at least the reservoir portion is at least sufficiently transparent to view the contents thereof.
3. An oral medicine dispenser as claimed in claim 1 or 2, wherein the end cap of
15 the dispensing tube portion is a frangible or severable end part of the dispensing tube portion.
4. An oral medicine dispenser as claimed in claim 1, 2 or 3, wherein the dispenser is of substantially unitary construction.
20
5. An oral medicine dispenser as claimed in claim 4, wherein the dispenser is formed of a plastics material by a form, fill and seal technique.
6. An oral medicine dispenser as claimed in claim 1, 2, 3, 4 or 5 wherein the device
25 is shaped to resemble a spoon, at least in profile.

7. A dispenser as claimed in any preceding claim, wherein the reservoir portion of the dispenser is generally hemispherical or at least having a substantially flat wall on one face and an opposing substantially domed wall.
- 5 8. A dispenser as hereinbefore described with reference to the accompanying drawings.

ABSTRACT OF THE INVENTION**ORAL MEDICINE DISPENSER**

The present invention provides an oral medicine dispenser for the administration of a single pre-measured dose, which dispenser comprises a body having a collapsible reservoir portion and an elongate dispensing tube portion extending from the reservoir portion, wherein the reservoir portion holds, in use, a single dose of a fluid oral medicament and the dispensing tube portion has an end cap, whereby on opening of the end cap the collapsible reservoir portion may be manually squeezed to collapse the reservoir portion sufficiently to dispense substantially all of, or at least a major part of the medicament dose through the dispensing tube portion.

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